What We Need to Eliminate HCV in the U.S.

— Alan Franciscus, Executive Director

The multimedia review journal Clinical Liver Disease, published a series of articles that provided important information about the tools needed to eliminate hepatitis C (HCV). This report is a review of the articles and is specific to the United States. It doesn’t address the political issues that are equally, if not more, important.

**Medicaid Treatment**¹ – State Medicaid programs are required by law to cover HCV direct-acting antiviral (DAA) therapy without restriction, but many states still limit coverage of these medications. These restrictions on DAA treatment are based on disease severity, sobriety (drug and alcohol) and the medical specialty providing treatment. These restrictions are not based on scientific evidence and lead to poorer treatment outcomes, higher future medical costs, and more importantly, they put patients at risk for worse health problems now and in the future. All patients should receive DAA therapy including those people who are eligible for Medicaid. To read more about HCV and Medicaid coverage to go: http://nvhr.org/hepatitis-c-state-medicaid-access

**Hepatitis C Vaccine Development**² – One of the most vexing problems in HCV has been the lack of the development of a protective vaccine against HCV. An effective vaccine to protect against HCV is one of the most important strategies to eliminate HCV. A vaccine will protect populations at highest risk of acute infection including people who inject drugs, healthcare workers exposed to blood or bodily fluids, people who receive hemodialysis (filters blood when the kidneys are no longer working) and other people who are at risk for HCV infection.

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The high mutation rate of the various parts of the hepatitis C virus is one of the biggest obstacles to developing a protective vaccine. There is a hint of a vaccine in the form of evidence of natural immunity in some people. Natural immunity against HCV is also found in laboratory studies in animal models, but scientists have not been able to replicate this process in an effective vaccine. Although there has been some progress, an effective vaccine remains elusive.

In the review article, the authors discuss various vaccine approaches. Due to the mutation process discussed above, researchers have had to develop models outside of the usual antibody specific type models used in other vaccines. Instead, other parts of the hepatitis C viral proteins are under study. One approach is to induce T cell-mediated immunity that causes CD8+ T cells (white blood cells that kill infectious cells) that are specific to HCV to clear the virus from the body.

Still, other researchers are focusing on non-infectious HCV-viral like particles to induce an antibody response. Currently, there are many vaccines in pre-clinical, phase 1 and phase 2 clinical studies. For more information and to enroll in vaccine studies, go to www.clinicaltrials.gov Type in HCV Vaccine.

Diagnostic Tools — In their review, the authors discuss the importance of developing effective diagnostic tools that can take a patient from the initial diagnosis of HCV (antibody test), confirmatory HCV RNA (viral load) to starting DAA therapy. Initially, the HCV test will decide if the infection is acute or chronic. Acute is the rapid onset of a recent infection that can be determined by risk factor assessment and various blood tests including an HCV antibody test. A positive HCV viral load after six months means that someone has chronic HCV.

If the person has a positive HCV viral load test, they can start the process of medical management (insurance, medical providers, medical tests, treatment and hopefully cure).

The problem with our medical system is that there is a large failure in tracking and care of patients from initial HCV antibody positive testing to starting DAA treatment and cure. The authors use an example of patient’s lost to follow-up:

- 715 (100%) patients had a positive HCV antibody positive test,
- 488 (68%) patients were tested HCV RNA (viral load),
- 388 (80%) tested were positive for HCV RNA,
- 223 (57%) started treatment,
- 201 (90%) completed treated and,
- 180 (46%) achieved a cure—a 90% cure rate.

In this analysis, out of 715 patients originally tested for HCV, only 223 started treatment.

The article discusses various HCV diagnostics tools (listed below). All of the patients need follow-up contact for the HCV viral load results and further action. However, initial testing can provide an opportunity for counseling and further medical care.
**Reflex Testing:** this process uses the leftover blood sample (tube) from an HCV antibody result to test for HCV viral load test. An important point to make is that the blood tubes need to be stored between the tests to prevent the blood samples from degrading. The costs are higher with this type of testing. Reflex testing would eliminate the need for a person to come back for another blood draw. A patient would have to be contacted for the results and follow-up medical care if the HCV viral load results are positive.

**Dried Blood Spot Testing (DBS):** A finger-prick whole blood sample is applied to a DBS card. It can be a single blot or applied in multiple blots on the same card. The DBS card can be returned via USPS mail or shipped with another carrier. The blood spots can be used to test for HCV antibody and HCV viral load. The HCV viral load has to be greater than 4 log IU/mL which is the vast majority of viral loads of people with HCV. Another advantage of DBS is that it can also test for HIV, hepatitis B (HBV) and syphilis. In addition to testing for other diseases, the DBS test would eliminate the need for further testing, and a patient could be contacted to start the process of seeking medical care.

**Point-of-Care and Rapid Diagnostic Tests:** The Oraquick finger-prick and oral swab tests allow for HCV antibody results in 20 minutes. If the HCV antibody is positive, a follow-up HCV viral load test would be necessary to confirm the diagnosis.

There is also a rapid HCV viral load test that uses a drop of whole blood to give results in 90 to 100 minutes. The rapid HCV viral load test is not approved in the United States. Outside of the United States, some countries use it to confirm chronic HCV.

**Challenges:** The authors point out that in every HCV diagnostic test there are limits based on the HCV population, and how to move them through the treatment continuum. For instance, in people who inject drugs, the DBS may be more useful than drawing a blood sample due to issues related to finding a vein to draw blood for a reflex test. People who are in prison need to have trained staff and linkage to care when released from prison. Non-native English speakers need translators for testing and linkage to care. The bottom line is that there is no one size fits all testing procedure.

**Acute HCV**

In the absence of a protective vaccine, an approach is needed to treat people newly infected with hepatitis C. Risk-factor assessment and various diagnostic tests can identify newly acquired HCV infection. In acute infection, 20% to 50% of people spontaneously clear the virus—that is their body will naturally clear the virus. If HCV RNA (viral load) is present after 6 months, the infection is chronic, and treatment with DAA therapy can be started. In most studies of DAA therapy, the treatment period of 8 weeks has produced cure rates approaching 100%. Other studies have found shorter treatment periods have produced similar cure rates.

**HCV Populations**

In the past, certain populations infected with HCV have had sub-optimal cure rates
with interferon-based therapies. Now that DAA-based therapy is available that is no longer the case:

- African Americans: near 95%
- HIV/HCV coinfection: up to 98% cure rates
- Renal (kidney) impairment: up to 98% cure rates
- Decompensate cirrhosis: up to 94% cure rates

People Who Inject Drugs (PWID): PWID comprise the main population who are at risk of acquiring HCV. The current rates of newly acquired infections are up to 70%. Treatment of PWIDs has produced up to 97% cure rates. The reinfection rates have been low. PWIDs are the group acutely infected with HCV; we must engage, treat and cure PWID to eliminate HCV.

Children 12 years of age and older: Treatment with DAA therapy is approved to treat children 12 years of age and older. The cure rate are 98% to 100%.

UNANSWERED TREATMENT QUESTIONS:

**HCV in Pregnancy:** Every year 29,000 pregnant women and 1,700 infants in the United States are estimated to be infected with HCV. Mother-to-child transmission occurs in 5.8% of mono-infected women and up to 10.8% of HIV/HCV coinfected women. The American Association for the Study of Liver Disease (AASLD) recommends a one-time HCV test for all pregnant women. However, Kentucky is the only state that requires by law that pregnant women are tested for HCV.

Currently, there is no guidance for the use of DAA therapy to treat pregnant women with HCV to prevent transmission of HCV from mother-to-child, and no drugs are approved to treat infants for HCV.

Children 12 years of Age and Under: The current recommendation is to wait until children are 12 years of age to treat or until more evidence is available to understand if DAA treatment is safe.

The article did not address the most important part to eliminate HCV—that is the political will to provide the resources on a local, state and national level. There is some movement towards the elimination of HCV in some countries. Some U.S. states have committed to eliminating HCV, but the U.S. Government has not committed—yet!

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Source:
Clinical Liver Disease – Free Access

1 Rationing Care: Barriers to Direct-Acting Antiviral Treatment in Medicaid Treatment Criteria—Phil Waters J.D., Tina Broder M.S.W., M.P.H.,
2 Hepatitis C Vaccine Development in the Era of Direct-Acting Antivirals – Matthew McConnell M.D., Joseph K. Lim M. D.
3 Hepatitis C Virus Diagnostics: The Road to Simplification – Jordan J. Feld M.D., M.P.H.
4 Hepatitis C Virus Standard of Care: A Rapid Evolution and Considerations for Acute Hepatitis C Virus - Tram T. Tran M.D.
5 PRO: Patients With Hepatitis C Virus With Pretreatment Metavir Stage 3 Fibrosis Do Not Require Hepatocellular Carcinoma Surveillance After Sustained Virological Response - Amoah Yeboah-Korang M.D., M.P.H., Nicole M. Gentile M.D., Claus J. Fimmel M.D.

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Sometimes it takes a hepatitis C diagnosis for us to pay attention to the fact that we each have a liver. We learn where the liver is, what it does, and how essential it is. However, the hepatitis C virus (HCV) affects more than just the liver. HCV affects the entire body, particularly the heart and cardiovascular system. Since February is American Heart Month, it is a perfect time to discuss the relationship between the liver and its neighbor, the heart. In particular, we will explore ways to improve cardiovascular health. This information is good for everyone, with or without hepatitis C.

Over the years, many studies have shown that people with hepatitis C have higher rates of heart disease and stroke. It makes sense, because hepatitis C is an inflammatory disease, and the cardiac system does not like excess inflammation. That said, keep in mind that the association between hepatitis C and cardiovascular disease does not prove that the virus causes the heart disease; it merely indicates a strong relationship.

Huh? If studies show that people with hepatitis C have a higher risk of heart disease and stroke, why doesn’t that mean that the virus causes cardiovascular disease? There could be other factors at play here. It could be that people with hepatitis C don’t exercise as much because they are too tired; or that they take medication that increases their risk.

What we do know is that when people successfully respond to hepatitis C treatment, their stroke and heart disease risk decreases. Is this because the virus is gone or is it because people feel better and are more active? We don’t know.

Although research on the link between hepatitis C and cardiovascular disease isn’t entirely conclusive, we do have evidence that taking care of your heart and health has multiple benefits. Physical activity and diet are strongly correlated with health, whether looking only at the liver, the heart, or another organ or system.

**THE FACTS**

Let’s start with some basic facts about heart disease:

- Heart disease is the leading cause of death for men and women.
- Someone has a heart attack every 40 seconds in the United States; someone dies from a heart disease-related event every minute in this country.

“Sometimes it takes a hepatitis C diagnosis for us to pay attention to the fact that we each have a liver.”

— Lucinda Porter, RN
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- Younger adults are at risk. In the United States, the rate of heart disease deaths are declining more slowly than they have in the past, especially among adults ages 35 to 64. In some parts of the country, death rates are increasing among adults in this age group. This age group also has seen a rise in risk factors related to heart disease, such as physical inactivity, tobacco use and high blood pressure.

- Heart disease and stroke are largely preventable conditions.

**RISK FACTORS**
About half of the adult population in the United States has at least one of the three top risk factors for heart disease. These are:

- High blood pressure
- High LDL cholesterol
- Smoking

Other significant risk factors include:

- Diabetes
- Overweight and obesity
- Poor diet
- Physical inactivity
- Excessive alcohol use

To this list, I’d add liver disease, whether it is hepatitis C, fatty liver disease or cirrhosis of any cause.

**CURRENT RECOMMENDATIONS**
In 2018, the U.S. Department of Health and Human Services (HHS) published the second edition of the Physical Activity Guidelines for Americans. The updates include more evidence, and thus incentive, showing the benefits of physical activity. There are also changes to the recommendations for physical activity for children. Here are the HHS recommendations for adults: “To attain the most health benefits from physical activity, adults need at least 150 to 300 minutes of moderate-intensity aerobic activity, like brisk walking or fast dancing, each week. Adults also need muscle-strengthening activity, like lifting weights or doing push-ups, at least 2 days each week.”

*A word to those who are overwhelmed or discouraged by the notion of exercise or other physical activity. I know that this sounds monumentally difficult. Please stick with me to the end of this article and read, “Let’s Get Practical.”*

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and 30 minutes) to 300 minutes (5 hours) a week of moderate-intensity, or 75 minutes (1 hour and 15 minutes) to 150 minutes (2 hours and 30 minutes) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity. Preferably, aerobic activity should be spread throughout the week.

- If able, do muscle-strengthening activities of moderate or greater intensity that involve all major muscle groups on 2 or more days a week, as these activities provide additional health benefits.

- If unable to meet the above key guidelines, engage in regular physical activity according to their abilities and avoid inactivity.

The latest studies show that physical activity has immediate health benefits. For example, physical activity can reduce anxiety and blood pressure and improve quality of sleep and insulin sensitivity. Do this more consistently, in time you may experience even more long-term health benefits.

Other benefits of physical activity include:

- Reduces risk of excessive weight gain and helps people maintain a healthy weight.
- Helps prevent 8 types of cancer (bladder, breast, colon, endometrium, esophagus, kidney, stomach, and lung).
- Decreases risk of dementia (including Alzheimer’s disease).
- Reduces risk of all-cause mortality, heart disease, stroke, high blood pressure, type 2 diabetes, and depression.
- Improves bone health, physical function, and quality of life.
- Lowers the risk of falls and injuries from falls in older adults.

HHS states, “New evidence shows that physical activity can help manage more health conditions that Americans already have. For example, physical activity can decrease pain for those with osteoarthritis, reduce disease progression for hypertension and type 2 diabetes, reduce symptoms of anxiety and depression, and improve cognition for those with dementia, multiple sclerosis, ADHD, and Parkinson’s disease.”

**THE BENEFITS**

Any amount of physical activity has some health benefits. If you do a small amount of moderate-to-vigorous physical activity throughout the day, your health may profit. According to HHS, the first edition of the Physical Activity Guidelines for Americans stated that only 10-minute bouts of physical activity counted toward meeting the guidelines. The second edition removes this requirement to encourage Americans to move more frequently throughout the day as they work toward meeting the guidelines.

**LET’S GET PRACTICAL**

Hear me out if you think that you can’t meet the exercise guidelines. I am 65 years old. I am not, nor have I ever been athletic. The truth is, I don’t particularly
like exercise and if I could skip it, I would. However, I love the benefits of exercise so much, that I endure the effort. These benefits include improved sleep, low blood pressure, strength, endurance, feeling energetic, no depression, and no diabetes.

Please don’t get the impression that I follow these guidelines all the time or do them perfectly. That is certainly not the case. However, I am devoted to the process, and when I fall off the exercise wagon, I get back on. I’ve been a regular exerciser for more than 30 years, so now it is a habit. I started out very slowly, which I highly recommend.

If you are just starting out, here are some tips:

• Talk to your doctor. It’s always a good idea to be sure you don’t have a medical reason that could be worsened by certain physical activities.

• Move more and sit less. Walking around a room every hour is better than sitting for 8 hours straight.

• Start where you are. If you can only walk a minute, then walk a minute. If you do this several times a day, you may be able to increase your endurance to 2 minutes.

• Start low, go slow. The goal is to succeed without ending up never wanting to exercise again. If you do too much, your physical fitness career may end abruptly. The purpose of this is to improve your health, and not to torture yourself. Increase duration and/or intensity gradually.

• Make it fun. Personally, I think that walking in a beautiful setting is more interesting than a treadmill. However, if poor weather forces me indoors, music or an audiobook will keep me on the treadmill.

• Be an encouraging self-coach. Never, ever berate yourself for anything, most especially for anything fitness-related.

• Find ways around the obstacles. Every night, I set out my workout clothes, shoes, water bottle and earphones. In the morning, I put them on and by then, I am committed enough to keep going. I don’t think I’ve ever put on this attire without actually completing a workout.

• Never give up. If I am not meeting a workout goal, it is probably because I haven’t figured out how to. By trying something different, my commitment stays firm, and in time, I discover ways to meet my goals.

The Bottom Line: If you have hepatitis C and want to improve your chances for survival, get treated. However, that is only a small part of good health. To maximize your chances of living a long and healthy life, be sure you are physically active for as long and as often as you can. And keep doing this for as long as you are able to.

Resources:
For more information about heart disease, visit the CDC’s website at [www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_heart_disease.htm](http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_heart_disease.htm)

For information about physical activity, check out [https://health.gov/paguidelines](https://health.gov/paguidelines)

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Hepatitis Headlines

Top Headlines in the News TODAY!

At Stanford, Term ‘Homosexual’ Will No Longer Be Used When Discussing Spread of Hepatitis

Stanford University students complained about the use of the word “homosexual” when discussing risk factors about the spread of hepatitis. This terminology was used in a hepatitis lab, and students found the term outdated and stigmatizing.

Additionally, some students were uncomfortable with the assertion that “Hep C and HIV are more prevalent and ‘more transmissible’ among gay folks as a blanket statement…” A student noted that, “It’s not untrue,” and requests more context be given about the threat to anyone who participates in anal sex, not just gay men.

Professor of Medicine Paul Kwo concurred. “In describing the MSM [Men who have Sex with Men] risk factor, the word homosexual was used in some of the groups which was neither accurate nor appropriate…We will address this specifically by updating both the Hepatitis Lab handout and facilitator notes and ensure input from students such that the learning experience is accurate, inclusive, and non-stigmatizing.”

Source: The College Fix, 12/17/2018

Adherence to ‘Healthy Eating Index’ Diet May Reduce Liver Cancer Risk

A 32-year follow-up study looked at three commonly used dietary pattern indices: The Alternative Healthy Eating Index-2010 (AHEI-2010), Alternate Mediterranean Diet (AMED), and Dietary Approaches to Stop Hypertension (DASH). Approaches to Stop Hypertension (DASH).

Participants with the highest scores on the AHEI-2010 diet had the lowest rates of hepatocellular carcinoma (HCC/liver cancer). Key features of the diets of those who had low rates of HCC were less red and processed meat consumption; higher intakes of vegetable, fruits, whole grains, dietary fiber, nuts and legumes, total folate, long-chain (n-3) fatty acids, and total vitamin D.

Further analysis found that light alcohol use, nut and legume consumption and polyunsaturated fatty acids intake correlated significantly with a lower risk for HCC.

Source: Helio, December 17, 2018
The first issue of this newsletter was in 1998. Since that time, hepatitis C-related news has seen many changes, many of them awesome. One of the unfortunate changes is the competition for funding. As a result, HCSP has decided that we are going to discontinue the HCV Advocate newsletter. The good news is that there is plenty of information available on the Internet to keep you up-to-date on everything related to hepatitis C.

The last issue of the HCV Advocate will be the March 2019 newsletter. Lucinda and I will reflect on some of the highlights throughout the years, and I will discuss where we will be taking the HCV Advocate web site in 2019.

Yours in Health,
Alan

Watch Our Video!
Click here to listen to a real patient talk about her journey from diagnosis to treatment to cure.

Don’t forget to check out the PackHealth – a free resource to help patients navigate their HCV treatment journey from applying for treatment to cure!

Do you have hepatitis C? Get support. Get answers.

• Get a personal Health Advisor to coach you on your journey.
• Develop a personalized plan – you set the goals, we’ll help you get there
• Find answers and accountability to get the results you want.
• Use the tools and guides we send you to track your progress.

Enroll online: packhealth.com/hcv

As easy as 1-2-3!
1. Enter your contact info
2. Use promo code: HCV2017
3. Get 3 months of membership free!

Questions? Call us at 888-255-2362
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